

REMARKS

Claim Rejections – 35 USC §102

Claims 50-55 and 63-79 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,063,088 to Winslow (hereafter “the ‘088 patent”). It is well established that “an invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claim.” Richardson v. Suzuki Motor Co. Ltd., 9 USPQ.2d 1913, 1920 (Fed. Cir. 1989).

The Applicant notes that the ‘088 patent to Winslow does not constitute prior art to the subject application under 35 U.S.C. §102(b). Specifically, the subject application has a priority date stemming from U.S. Application Serial No. 09/181,353, now U.S. Patent No. 6,174,311, of October 28, 1998. However, the ‘088 patent was not published or patented until May 16, 2000. Accordingly, Winslow does not constitute prior art to the subject application under 35 U.S.C. §102(b). Nevertheless, as set forth below, the Applicant submits that the pending claims are patentable over the ‘088 patent.

Independent Claim 50 and Dependent Claims 51-55, 63-68, 70 and 81

Independent claim 50 has been amended to recite, among other elements and features, a retractor blade and a retractor body provided with first and second enlarged edges extending in an axial direction and defining a channel therebetween adapted to engagingly receive the retractor blade, with “the retractor blade received within the channel and nested between and engaged with the first and second enlarged edges to maintain the retractor blade in a predetermined position relative to the retractor body”, and with “the channel being open in lateral direction between the first and second enlarged edges and the retractor blade including a concave shape extending continuously from the first enlarged edge to the second enlarged edge and open in a lateral direction to provide an unobstructed view of a retracted area of a surgical site”. Support for the amendments to independent claim 50 is found, for example, in paragraphs [0153]-[0156] and Figures 28-30 of the published version of the subject application.

Also, previously presented independent claim 55 and dependent claims 65 and 70 have been rewritten to depend from independent claim 50, and dependent claim 68 has been rewritten to depend from dependent claim 55. Additionally, claim 66 has been amended to include the subject matter recited in the previously presented version of dependent claim 69, and dependent claim 69 has been cancelled without prejudice. Further, claims 51, 54, 55, 65-68 and 70 have been amended in view of the amendments to independent claim 50 and/or to improve their form.

The Office Action asserts that the '088 patent discloses "a spinal assembly retractor (120, Fig. 3) having a retractor cutting portion that incorporates a blade portion (204), in a channel (218) that provides an unobstructed view and is adapted to engagingly receive the retractor blade in use and in a lateral position. Winslow also includes (sic) first and second enlarged edges (120) that extend in an axial direction to form a channel. . . . The retractor body also comprises a supporting member (106) that is used for attaching a retractor pin (110). The supporting member also defines a hollow tube (108) for the retractor pin, and wherein the channel may be considered concave." (See pages 2-3 of the Office Action).

As an initial matter, it is respectfully submitted that the drill bit 204 is not a "retractor blade" and does not comprise a blade portion, as would be appreciated by those having skill in the art. Instead, the '088 patent teaches that the drill bit 204 is structured to "form a generally circular bore in the bone structures." (See column 6, line 67). Moreover, to the extent that the drill bit 204 is inserted through the retractor 100, which retracts the tissue at the surgical site and distracts the adjacent vertebral bodies before the drill bit 204 is positioned within the retractor 100, the Applicant submits that the drill bit 204 does not retract anything. Accordingly, the '088 patent does not teach, suggest or disclose a retractor blade, as that feature is set forth in the subject application and recited in independent claim 50.

Additionally, even assuming arguendo that the drill bit 204 could be construed as a retractor blade, independent claim 50 is still patentably distinguishable over the '088 patent. Notably, no element of the retractor 100, including either the retractor sleeve 102 or the drill extension sleeve 206, includes "first and second enlarged edges extending in an axial direction and defining a channel therebetween", with "the retractor blade nested between and engaged with the first and second enlarged edges to maintain the retractor blade in a predetermined position relative to the retractor body". Specifically, the drill bit 204 is not nested between or

engaged with first and second enlarged edges of any component or element of the retractor 100 to maintain the drill bit in a predetermined position relative to a retractor body. Furthermore, no component or element of the retractor 100 defines a channel that is “open in lateral direction” between first and second enlarged edges, with the open channel and the retractor blade being shaped “to provide an unobstructed view of a retracted area of a surgical site.” To the contrary, the passageway 104 of the retractor sleeve 102 is entirely enclosed, and the drilling instrument 200 entirely fills the passageway 104. Accordingly, the retractor 100 does not provide an unobstructed view along the drill bit 204 of a retracted area of a surgical site. Instead, the drilling instrument 200 is positioned within the passageway 104 of the retractor sleeve 102 and obstructs the view into the passageway 104, and which also obstructs the view of any area of a surgical site which is retracted by the retractor sleeve 102. Additionally, as illustrated in Figures 13-17, the retractor arms 120 are inserted between the adjacent vertebrae V_1 , V_2 , until the distal end of the retractor sleeve 102 contacts the vertebrae V_1 , V_2 , consequently blocking any view of a retracted area within the passageway 104.

Furthermore, the ‘088 patent fails to disclose or suggest the language recited in independent claim 50 regarding “the retractor blade including a concave shape extending continuously from the first enlarged edge to the second enlarged edge and open in a lateral direction to provide an unobstructed view of a retracted area of a surgical site”. With regard to the drill bit 204, no portion of the drill bit 204 has “a concave shape extending continuously from the first enlarged edge to the second enlarged edge”, as recited in independent claim 50. Indeed, the drill bit 204 has a circular outer cross section, and does not define any portion that could be construed as having “a concave shape”. To the contrary, the entire outer profile of the drill bit 204 has a convex shape. Moreover, the drill bit 204 does not have a concave shape that is “open in a lateral direction to provide an unobstructed view of a retracted area of a surgical site”. To the contrary, the drill bit 204 occupies virtually the entire inner region of the retractor 100 and is not open in a lateral direction, thereby obstructing the view of the surgical site. Accordingly, the ‘088 patent fails to disclose or suggest each of the elements and features recited in independent claim 50. Additionally, as indicated above, the Office Action has construed the opposed retractor arms 120 of the retractor 100 as constituting “first and second enlarged edges” of a retractor body. However, no portion of the drilling instrument 200 has “a concave shape

extending continuously from the first enlarged edge to the second enlarged edge” and which is configured to provide an unobstructed view of a retracted area of a surgical site, as recited in independent claim 50.

For at least these reasons, the Applicant submits that the ‘088 patent does not teach or suggest each of the elements and features recited in independent claim 50, as now amended. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 50 as being anticipated by the ‘088 patent and requests allowance of the same.

Claims 51-55, 63-68, 70 and 81 depend either directly or indirectly from independent claim 50 and are submitted to be patentable for at least the reasons set forth above in support of the patentability of independent base claim 50. Additionally, further reasons support the patentability of these claims.

For example, claim 67 and 68 each recite that the first and second supporting members attached to the first and second retractor pins also “define the first and second enlarged edges of the retractor body engaged with the retractor blade”. Support for the amendments to dependent claims 67 and 68 is found, for example, in paragraph [0154] and Figures 28 and 29 of the published version of the subject application. With regard to the ‘088 patent, the Office Action asserts that the first and second rails 106 extending along the retractor sleeve 102 are used for attaching a retractor pin 110. However, the first and second rails 106 that receive the retractor pins 110 do not also “define the first and second enlarged edges of the retractor body engaged with the retractor blade”. The Office Action has construed the drill bit 204 as comprising a retractor blade. However, no portion of the drill bit 204 is in any way engaged with first and second rails 106. Indeed, the drill bit 204 is positioned within the interior passageway 104 of the retractor tube 100, whereas the first and second rails 106 are positioned along the exterior of the retractor tube 100. Accordingly, no portion of the drill bit 204 is engaged with, or is even capable of engaging, any portion of the drill bit 204. Accordingly, dependent claims 67 and 68 recite features that are neither disclosed nor suggested by the ‘088 patent.

Additionally, new dependent claim 81 recites that “the retractor blade includes a distractor tip sized and shaped for insertion into an intervertebral space for distraction of the intervertebral space, the distractor tip having a width corresponding to a distracted height of the intervertebral space and a rounded distal end transitioning to the width of the distractor tip to

facilitate insertion into and the distraction of the intervertebral space.” Support for new dependent claim 81 is found, for example, in previously presented dependent claim 79 and paragraph [0154] and Figures 28 and 30a of the published version of the application.

The Applicant notes that the Office Action does not set forth grounds regarding the rejection of dependent claim 79, which recites subject matter that has been carried over into new dependent claim 81. Specifically, the Office Action does not make any reference whatsoever regarding what portion of the drill bit 204 (which has been construed as a blade portion) constitutes “a distractor tip sized and shaped for insertion into an intervertebral space for distraction of the intervertebral space”, as recited in new dependent claim 81 and as previously presented dependent claim 79. Even assuming *arguendo* that the drill bit 204 could be construed as a “retractor blade”, the drill bit 204 clearly does not include a distractor tip sized and shaped for insertion into and distraction of an intervertebral space. Rather, the ‘088 patent discloses that the drill bit 204 is configured to form a bore between the vertebral bodies, and not to distract the disc space. Additionally, the opposed retractor arms 120 of the retractor 100 distract the intervertebral space before the drill bit 204 engages the vertebral bodies. Moreover, the anchoring members 110 engage each of the adjacent vertebral bodies after the retractor arms 120 are inserted therebetween, thereby fixing the vertebral bodies relative to each other and prohibiting additional distraction of the intervertebral space. Accordingly, the subject matter recited in the previously presented version of dependent claim 79 and carried over into new dependent claim 81 is not disclosed in the ‘088 patent, and is therefore submitted to be patentable over the ‘088 patent.

Nevertheless, dependent claim 81 also recites language that further clarifies the features which are “sized and shaped for insertion into an intervertebral space for distraction of the intervertebral space”. Specifically, dependent claim 81 recites “the distractor tip having a width corresponding to a distracted height of the intervertebral space and a rounded distal end transitioning to the width of the distractor tip to facilitate insertion into and the distraction of the intervertebral space”. Once again, the ‘088 patent fails to disclose or suggest such features.

Independent Claim 71 and Dependent Claims 73-80

The Applicant has amended independent claim 71 to include the subject matter recited in previously presented dependent claim 72 and to recite, among other elements and features, a retractor body “having a support portion including first and second support members defining a channel therebetween and each support member having an enlarged edge extending in an axial direction along the channel”, a retractor blade received within the channel and “nested between and engaged with each of the enlarged edges such that the retractor blade is held in a predetermined position relative to the retractor body”, and with “the retractor blade having a shape complementary to a shape of the support portion and the channel being open in lateral direction between the enlarged edges and the retractor blade including a concave shape extending continuously from a first of the enlarged edges to a second of the enlarged edges and open in a lateral direction to provide an unobstructed view of a retracted area of a surgical site.” Support for the amendments to independent claim 71 is found, for example, in paragraphs [0153]-[0156] and Figures 28-30 of the published version of the subject application. Dependent claim 72 has been cancelled without prejudice, and dependent claim 73 has been rewritten to depend from dependent claim 71.

As indicated above with regard to independent claim 50, it is respectfully submitted that the drill bit 204 is not a “retractor blade” and does not comprise a blade portion, as would be appreciated by those having skill in the art. Furthermore, even assuming arguendo that the drill bit 204 could be construed as a retractor blade, independent claim 71 is still patentably distinguishable over the ‘088 patent. Notably, no element of the retractor 100, including either the retractor sleeve 102 or the drill extension sleeve 206, includes “first and second enlarged edges extending in an axial direction and defining a channel therebetween”, with “the retractor blade nested between and engaged with the first and second enlarged edges to maintain the retractor blade in a predetermined position relative to the retractor body”. Specifically, the drill bit 204 is not nested between or engaged with first and second enlarged edges of any component or element of the retractor 100 to maintain the drill bit 204 in a predetermined position relative to a retractor body. Furthermore, no component or element of the retractor 100 defines a channel that is “open in lateral direction” between first and second enlarged edges, with the open channel and the retractor blade being shaped “to provide an unobstructed view of a retracted area of a

surgical site.” To the contrary, the passageway 104 of the retractor sleeve 102 is entirely enclosed, and the drilling instrument 200 entirely fills the passageway 104. Accordingly, the retractor 100 does not provide an unobstructed view along the drill bit 204 of a retracted area of a surgical site. Instead, the drilling instrument 200 is positioned within the passageway 104 of the retractor sleeve 102 and obstructs the view into the passageway 104, and which also obstructs the view of any area of a surgical site which is retracted by the retractor sleeve 102. Additionally, as illustrated in Figures 13-17, the retractor arms 120 are inserted between the adjacent vertebrae V_1 , V_2 , until the distal end of the retractor sleeve 102 contacts the vertebrae V_1 , V_2 , consequently blocking any view of a retracted area within the passageway 104.

Furthermore, the ‘088 patent fails to disclose or suggest the language recited in independent claim 71 regarding “the retractor blade including a concave shape extending continuously from a first of the enlarged edges to a second enlarged edges and open in a lateral direction to provide an unobstructed view of a retracted area of a surgical site”. With regard to the drill bit 204, no portion of the drill bit 204 has “a concave shape extending continuously from a first of the enlarged edges to a second of the enlarged edges”, as recited in independent claim 71. Indeed, the drill bit 204 has a circular outer cross section, and does not define any portion that could be construed as having “a concave shape”. To the contrary, the entire outer profile of the drill bit 204 has a convex shape. Moreover, the drill bit 204 does not have a concave shape that is “open in a lateral direction to provide an unobstructed view of a retracted area of a surgical site”. To the contrary, the drill bit 204 occupies virtually the entire inner region of the retractor 100 and is not open in a lateral direction, thereby obstructing the view of the surgical site. Accordingly, the ‘088 patent fails to disclose or suggest each of the elements and features recited in independent claim 71. Additionally, as indicated above, the Office Action has construed the opposed retractor arms 120 of the retractor 100 as constituting “first and second enlarged edges” of a retractor body. However, no portion of the drilling instrument 200 has “a concave shape extending continuously from a first of the enlarged edges to a second of the enlarged edges” and which is configured to provide an unobstructed view of a retracted area of a surgical site, as recited in independent claim 71.

For at least these reasons, the Applicant submits that the ‘088 patent does not teach or suggest each of the elements and features recited in independent claim 71, as now amended.

Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 71 as being anticipated by the '088 patent and requests allowance of the same.

Claims 73-80 depend either directly or indirectly from independent claim 71 and are submitted to be patentable for at least the reasons set forth above in support of the patentability of independent base claim 71. Moreover, dependent claims 73-80 are patentable over the '088 patent for additional reasons as well.

For example, dependent claim 79 has been amended to recite that the retractor blade includes a distractor tip sized and shaped for insertion into an intervertebral space for distraction of the intervertebral space, with "the distractor tip having a width corresponding to a distracted height of the intervertebral space and a rounded distal end transitioning to the width of the distractor tip to facilitate insertion into the intervertebral space". Support for the amendment to dependent claim 79 is found, for example, in paragraph [0154] and Figures 28 and 30a of the published version of the application.

As indicated above with regard to dependent claim 81, the Applicant notes that the Office Action does not set forth grounds regarding the rejection of the previously presented version of dependent claim 79. Specifically, the Office Action does not make any reference whatsoever to what portion of the drill bit 204 (which has been construed as a blade portion) constitutes "a distractor tip sized and shaped for insertion into an intervertebral space for distraction of the intervertebral space", as recited in the previously presented version of dependent claim 79. Even assuming arguendo that the drill bit 204 could be construed as a "retractor blade", the drill bit 204 clearly does not include a distractor tip sized and shaped for insertion into and distraction of an intervertebral space. Rather, the '088 patent discloses that the drill bit 204 is configured to form a bore between the vertebral bodies, and not to distract the disc space. Additionally, the opposed retractor arms 120 of the retractor 100 distract the intervertebral space before the drill bit 204 engages the vertebral bodies. Moreover, the anchoring members 110 engage each of the adjacent vertebral bodies after the retractor arms 120 are inserted therebetween, thereby fixing the vertebral bodies relative to each other and prohibiting additional distraction of the intervertebral space. Accordingly, the subject matter recited in the previously presented version of dependent claim 79 is not disclosed in the '088 patent, and is therefore submitted to be patentable over the '088 patent.

Nevertheless, dependent claim 79 has been amended to recite additional language that further clarifies the features which are “sized and shaped for insertion into an intervertebral space for distraction of the intervertebral space”. Specifically, dependent claim 79 recites “the distractor tip having a width corresponding to a distracted height of the intervertebral space and a rounded distal end transitioning to the width of the distractor tip to facilitate insertion into and the distraction of the intervertebral space”. Once again, the ‘088 patent fails to disclose or suggest such features.

Additionally, new dependent claim 80 recites “wherein the first and second support members defining the first and second openings that receive the first and second pins also define the first and second enlarged edges of the retractor body.” The subject matter recited in dependent claim 80 is based on the subject matter recited in dependent claims 67 and 68, and is supported, for example, in paragraph [0154] and Figures 28 and 29 of the published version of the subject application. As indicated above with regard to dependent claims 67 and 68, the Office Action asserts that the first and second rails 106 extending along the retractor sleeve 102 are used for attaching a retractor pin 110. However, the first and second rails 106 that define the longitudinal openings 108 which receive the retractor pins 110 do not also define “the first and second enlarged edges of the retractor body”. The Office Action has construed the drill bit 204 as comprising a retractor blade. However, no portion of the drill bit 204 is in any way engaged with first and second rails 106. Indeed, the drill bit 204 is positioned within the interior passageway 104 of the retractor tube 100, whereas the first and second rails 106 are positioned along the exterior of the retractor tube 100. Accordingly, no portion of the drill bit 204 is engaged with, or is even capable of engaging, any portion of the drill bit 204. Accordingly, dependent claim 80 recites features that are neither disclosed nor suggested by the ‘088 patent.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the Applicant's application is now in condition for allowance with pending claims 50-55, 63-68, 70, 71 and 73-81.

Reconsideration of the subject application is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

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